

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10123 and -10124, CMS-10147, CMS-10252, CMS-10340, CMS-R-235, CMS-R-268 and CMS-10519]

Agency Information Collection Activities: Submission for OMB Review; Comment Request ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]:

ADDRESSES: When commenting on the proposed information collections, please reference the

document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: *OIRA_submission@omb.eop.gov*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

http://www.cms.hhs.gov/PaperworkReductionActof1995.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326. SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the Federal Register concerning each

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proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

- 1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Fast Track Appeals Notices: NOMNC/DENC; Use: Providers shall deliver a Notice of Medicare (Provider) Non-Coverage (NOMNC) to beneficiaries, enrollees, or both beneficiaries and enrollees no later than two days prior to the end of Medicarecovered services in skilled nursing facilities, home health agencies, comprehensive outpatient rehabilitation facilities, and hospices. Beneficiaries, enrollees or both beneficiaries and enrollees will use this information to determine whether they want to appeal the service termination to their Quality Improvement Organization (QIO). If the beneficiaries, enrollees or both beneficiaries decide to appeal, the Medicare provider or health plan will send the QIO and appellant a Detailed Explanation of Non-Coverage (DENC) detailing the rationale for the termination decision. Form Number: CMS-10123 and -10124 (OMB control number: 0938-0953); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 24,915; Total Annual Responses: 5,347,980; Total Annual Hours: 927,901. (For policy questions regarding this collection contact Janet Miller at 404-562-1799).
- 2. <u>Type of Information Collection Request</u>: Extension of a currently approved collection; <u>Title of Information Collection</u>: Medicare Prescription Drug Coverage and Your Rights; <u>Use</u>: Through the delivery of this standardized notice, Part D plan sponsors' network pharmacies are

in the best position to inform enrollees (at the point of sale) about how to contact their Part D plan if their prescription cannot be filled and how to request an exception to the Part D plan's formulary. The notice restates certain rights and protections related to the enrollees Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered. Form Number: CMS-10147 (OMB control number: 0938-0975); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits; Number of Respondents: 56,000; Total Annual Responses: 37,620,000; Total Annual Hours: 626,749. (For policy questions regarding this collection contact Kathryn M. Smith at 410-786-7623).

3. Type of Information Collection Request: Extension of a currently approved collection;
Title of Information Collection: Data Use Agreement (DUA) Certificate of Disposition (COD) for Data Acquired from the Centers for Medicare & Medicaid Services; Use: The Data Use Agreement (DUA) Certificate of Disposition (COD) is required to close out the release of the data under the DUA and to ensure the data are destroyed and not used for another purpose without written authorization from CMS. The Health Insurance Portability and Accountability Act (HIPAA) of 1996, §1173(d) (Security Standards for Health Information) requires CMS to protect Personally Identifiable Information (PII). Additionally, the Federal Information Security Management Act (FISMA) of 2002, §3544 (b) (Federal Agency Responsibilities – Agency Program) also requires CMS to develop policies and procedures for the protection and destruction of sensitive data to include PII. Form Number: CMS-10252 (OMB control number: 0938-1046); Frequency: Biennial; Affected Public: Private Sector - Business or other for-profits, Not-for-profit institutions; Number of Respondents: 500; Total Annual Responses: 1000; Total

<u>Annual Hours:</u> 84. (For policy questions regarding this collection contact Sharon Kavanagh at 410-786-5441.)

- 4. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Collection of Encounter Data from Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and Pace Organizations; Use: We collect encounter data or data on each item or service delivered to enrollees of Medicare Advantage (MA) plans offered by MA organizations. MA organizations currently obtain this data from providers. We collect this information using standard transaction forms and code sets. We will use the data for determining risk adjustment factors for payment, updating the risk adjustment model, calculating Medicare DSH percentages, Medicare coverage purposes, and quality review and improvement activities. The data is also used to verify the accuracy and validity of the costs claimed on cost reports. For PACE organizations, encounter data would serve the same purpose it does related to the MA program and would be submitted in a similar manner. The information collection request has been revised subsequent to the publication of the 60-day **Federal Register** notice (June 2, 2014; 79 FR 31336). Form Number: CMS-10340 (OMB control number: 0938-1152); Frequency: Weekly; Affected Public: Private sector - Business or other for-profits; Number of Respondents: 683; Total Annual Responses: 516,493,635; Total Annual Hours: 34,433 (For policy questions regarding this collection contact Michael Massimini at 410-786-1566).
- 5. <u>Type of Information Collection Request:</u> Revision of a currently approved collection; <u>Title of Information Collection:</u> Data Use Agreement (DUA) Certificate of Disposition for Data

 Acquired from the Centers for Medicare & Medicaid Services (CMS); <u>Use</u>: The Privacy Act of

1974 allows for discretionary releases of data maintained in Privacy Act protected systems of records under §552a(b) (Conditions of Disclosure). The mandate to account for disclosures of data under the Privacy Act is found at §552a(c)(Accounting of Certain Disclosures). This section states that certain information must be maintained regarding disclosures made by each agency. This information is: Date, Nature, Purpose, and Name and Address of Recipient. Section 552a(e) sets the overall Agency Requirements that each agency must meet in order to maintain records under the Privacy Act. The Data Use Agreement (DUA) form is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act for disclosures that contain PII. The DUA form also provides data requestors and custodians with a formal means to agree to the data protection and destruction statutory and regulatory requirements of CMS' PII data. The Health Insurance Portability and Accountability Act (HIPAA) of 1996, §1173(d) (Security Standards for Health Information) requires CMS to protect Personally Identifiable Information (PII). Additionally, the Federal Information Security Management Act (FISMA) of 2002, §3544 (b) (Federal Agency Responsibilities – Agency Program) also requires CMS to develop policies and procedures for the protection and destruction of sensitive data to include PII. The information collected by the DUA form is used by CMS to track disclosures, conditions for disclosure, accounting of disclosures and agency requirements dictated by the Privacy Act, HIPAA and FISMA. Form Number: CMS-R-235 (OMB control number: 0938-0734); Frequency: Annually; Affected Public: Private Sector -Business or other for-profits and Not-for-profit institutions; Number of Respondents: 9220; Total Annual Responses: 9220; Total Annual Hours: 2740. (For policy questions regarding this collection contact Sharon Kavanagh at 410-786-5441.)

- 6. Type of Information Collection Request: Extension of a currently approved collection;

 Title of Information Collection: Survey Tool for www.medicare.gov and www.cms.hhs.gov;

 Use: The Balanced Budget Act of 1997 states that the Secretary of Health and Human Services shall maintain a website to provide information about CMS activities, programs and topics related to its services. The submission is for OMB authorization to collect data on the reactions of users of the websites through the survey tool. We will use the data to improve the websites so that they can best serve the needs of their users. Information collected from the survey will be used to make improvements to the sites to make them more user-friendly. Form Number: CMS-R-268 (OMB control number: 0938-0756); Frequency: Annual; Affected Public: Individuals or households; Number of Respondents: 7,000; Total Annual Responses: 4,900; Total Annual Hours: 817. (For policy questions regarding this collection contact Kymeiria Ingram at 410-786-8431.)
- 7. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support; Use: The incentive and reporting programs have data integrity issues, such as rejected and improper payments. This four year project will evaluate incentive payment information for accuracy and identify improper payments, with the goal of recovering these payments. Additionally, based on the project's results, recommendations will be made so that we can avoid future data integrity issues.

Data submission, processing, and reporting will be analyzed for potential errors, inconsistencies, and gaps that are related to data handling, program requirements, and clinical

quality measure specifications of PQRS and eRx program. Surveys of Group Practices,
Registries, and Data Submission Vendors (DSVs) will be conducted in order to evaluate the
PQRS and eRx Incentive Program. Follow-up interviews will occur with a small number of
respondents. Form Number: CMS-10519 (OMB control number: 0938-NEW); Frequency:
Annually; Affected Public: Business or other for-profits; Number of Respondents: 115; Total
Annual Responses: 115 Total Annual Hours: 201. (For policy questions regarding this collection
contact Sungsoo Oh at 410-786-7611.)

Dated: September 2, 2014.	
	Martique Jones,
	Director, Regulations Development Group,
	Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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